

UNITED STATES DISTRICT COURT  
DISTRICT OF MINNESOTA

In re: BAIR HUGGER FORCED AIR  
WARMING DEVICES PRODUCTS  
LIABILITY LITIGATION

MDL No. 15-2666 (JNE/DTS)

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This Document Relates To:  
*All Cases*

**PLAINTIFFS' RESPONSE TO  
THE COURT'S MAY 6, 2019  
ORDER REGARDING  
RECONSIDERATION OF  
GENERAL CAUSATION**

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**INTRODUCTION**

The Court's May 6, 2019 Order poses three questions that involve challenges to specific causation testimony that 3M did not raise in its motion for reconsideration and assumptions about the weight to be given to individual studies. There is no new scientific revelation or compelling circumstance that would justify reversal of the Court's prior orders admitting the testimony of Plaintiffs' medical experts. And there is no question that Plaintiffs' medical experts followed reliable and accepted methodologies in reaching their opinions. 3M's attacks boil down to mere disagreement with Plaintiffs' medical experts' conclusion that Bair Hugger can cause deep joint infection. The Eighth Circuit has repeatedly cautioned, however, that the jury, not the district court, must resolve that debate.

The first issue raised by the Court misconstrues the definition of general causation by asking Plaintiffs to identify a methodology to establish that Bair Hugger is "*the* most probable cause or source of the infection in *all* cases." The general causation inquiry, however, is not whether Bair Hugger is the *primary* cause of deep joint infection but rather

whether it is *a* cause. Nonetheless, the Court asks Plaintiffs to describe the appropriate methodology for identifying Bair Hugger as the most probable cause. The Court's question therefore conflates general causation and specific causation. In addition, the issue of specific causation is not before the Court because 3M did not raise it in moving for reconsideration. Plaintiffs nevertheless describe in detail the methodologies their medical experts have used to opine about general *and* specific causation. As the Court has previously determined, these methodologies easily satisfy *Daubert*'s liberal requirements.

The Court's second question assumes that the findings of the Jeans study confounded the results of the McGovern study. The assumption is misplaced. Jeans did not analyze the effect of MSSA screening on Bair Hugger patients; nor did it analyze the effect of MSSA screening on deep joint infection—the injury at issue in this litigation. Instead, the study lumped together deep joint and superficial skin infections. 3M's own experts not only concede that Jeans does not prove causation with respect to MSSA screening and infection; they also agree that the study's failure to analyze deep joint infection rates does not allow them to conclude that MSSA screening confounded the McGovern study. In fact, Dr. Borak admits that Bair Hugger potentially confounded Jeans. For similar reasons, Dr. Samet has concluded that this new study does *not* change his opinion that Bair Hugger is a substantial contributing cause of deep joint infection. Given the consensus on both sides that Jeans does not confound McGovern, the Court has no scientific basis to rule otherwise.

Assuming for the sake of argument that the McGovern study no longer reliably supports Plaintiffs' allegations involving hip arthroplasties, the Court's third question asks Plaintiffs to identify other evidence of causation. This assumption, however, goes too far.

Rejecting a statistically significant, peer-reviewed, and published study with a known error rate is utter anathema to how scientists interpret and weigh data. Moreover, even if the McGovern study merited little or no weight, Plaintiffs' medical experts rely on numerous other lines of experimental and epidemiological evidence that collectively provides a coherent mechanism to explain Bair Hugger's role in causing infection. Because Plaintiffs have offered reliable expert testimony from world-renowned experts that Bair Hugger can and does cause deep joint infection, the Court should deny the motion for reconsideration.

### **BACKGROUND**

Discovery in this MDL occurred in two separate phases: general causation, and, if Plaintiffs offered reliable evidence to show that Bair Hugger can cause deep joint infection, then specific causation. Plaintiffs met their initial burden by offering reliable expert testimony establishing general causation, and the Court properly denied 3M's *Daubert* and summary judgment motions, allowing the MDL to proceed to the specific causation phase.

In August 2018, 3M requested leave to move for reconsideration of the Court's general causation rulings based on "new evidence." After the Court granted 3M's request, Plaintiffs sought leave to conduct discovery on the "new evidence," but the Court denied the request. Plaintiffs filed their memorandum opposing 3M's motion for reconsideration of general causation the next day. The pending motion thus relates to the Court's rulings on *general causation*, not *specific causation*, which involves distinct legal issues that arise only in the context of an individual case. Because Plaintiffs have offered reliable expert testimony from highly-qualified experts that Bair Hugger can cause deep joint infection in total knee and hip arthroplasty procedures, the Court should deny 3M's motion

notwithstanding the three additional questions it has posed to the parties. Dkt. 1905 at 1-2.

## ARGUMENT

### **I. Although 3M Has Not Moved for Reconsideration of Specific Causation, Plaintiffs’ Experts Have Used Reliable Methods in Opining that Bair Hugger Can Generally Cause DJI and Has In Fact Caused DJI in Specific Procedures**

The Court’s first question acknowledges that “differential diagnosis or etiology is a well-recognized technique that identifies the cause of a medical condition by eliminating the likely causes until the most probable cause is isolated.” Dkt. 1905 at 2. Nevertheless, the Court asks Plaintiffs to identify a reliable method for determining that Bair Hugger is the most probable cause of infection and to explain how that method satisfies *Daubert*. *Id.*

#### **A. 3M’s Motion Relates to General Causation, Not Specific Causation.**

As the Court knows, 3M has moved for reconsideration of general causation. Dkt. 1719. The Court’s question, however, asks Plaintiffs to identify a method to support the allegation that “Bair Hugger is the most probable cause or source of the infection in all cases.” Dkt. 1905 at 1–2. The general causation question under *Daubert* is not whether Bair Hugger is the *only* or *most significant* cause of infection in *all* cases; it is whether Bair Hugger is *capable* of causing deep joint infection (“DJI”) in *general*. See *Reference Manual on Scientific Evidence*, 3d ed. 623, 627 (Federal Judicial Center 2011) (defining general and specific causation). Almost every disease, including DJI, has more than one cause. The general causation inquiry here is whether Bair Hugger is *one* of them. The Court’s first question thus puts the cart before the horse. *Id.* at 552 n.5 (“This terminology and the distinction between general and specific causation are widely recognized in court opinions.”); *Junk v. Terminix Co.*, 628 F.3d 439, 450 (8th Cir. 2010) (“General causation

is a showing that the [product] is capable of causing the type of harm from which the plaintiff suffers. Specific causation is evidence that the [product] in fact caused the harm.”).

Understanding that general and specific causation are discrete inquiries involving distinct methodologies and different types of proof is essential to analyzing both the scope of 3M’s motion for reconsideration and the reliability of Plaintiffs’ medical experts’ testimony. Whereas *specific causation* focuses on the details of an individual plaintiff’s treatment and risk factors, *general causation* draws from multiple lines of experimental, observational, and mechanistic evidence. *See Reference Manual* at 716. As explained more fully below, Plaintiffs’ medical experts have used a multitude of well-established scientific methods in determining that Bair Hugger is capable of causing DJI. On the other hand, the same experts have applied different methods in concluding that Bair Hugger specifically caused an individual plaintiff’s DJI. In the first bellwether, for instance, the Court properly recognized—just as it does now—that Plaintiffs’ medical experts used the “well-recognized technique” of differential diagnosis to determine that Bair Hugger caused Mr. Gareis’s DJI. Dkt. 1905 at 1 (citing *Turner v. Iowa Fire Equip. Co.*, 229 F.3d 1202, 1208 (8th Cir. 2001)); *see Gareis v. 3M Co.*, No. 16-cv-04187, Dkt. 111 (denying motion to exclude Drs. Jarvis and Stonnington because they conducted a proper differential etiology).

*1. Plaintiffs’ Medical Experts Used Numerous Reliable Scientific Methodologies in Opining that Bair Hugger Can Cause DJI.*

To the extent the Court’s threshold question properly focuses on general causation, Plaintiffs’ medical experts used a variety of reliable methodologies to conclude that Bair Hugger can cause DJI. Dr. Samet used the Bradford Hill criteria among other established

methods of causal inference. *See* Dkt. 1813-2. Dr. Jarvis, however, invoked the “gold standard” methodology that he used for nearly two decades at the CDC for investigating nosocomial infections. *See* Dkt. 1813-1. Still further, Dr. Stonnington relied on his clinical experience as an orthopedic surgeon as well as the great weight of scientific literature. *See* Dkt. 1813-3. Each and every one of these methods is reliable under *Daubert* and Rule 702, as Plaintiffs explained in opposing 3M’s initial *Daubert* motion and subsequent motion for reconsideration of general causation. *See* Dkt. 879 at 47–69; Dkt. 1786 at 45–49. Indeed, 3M has *never* attacked any of the methodologies that Plaintiffs’ medical experts used in opining that Bair Hugger can cause DJI—only their conclusions. *See* Dkt. 1719 at 33–35; *cf. Bonner v. ISP Techs. Inc.*, 259 F.3d 924, 929 (8th Cir. 2001) (declaring that the novelty of a scientific conclusion goes to the weight of an expert’s testimony, not its admissibility).

In addition, all of Plaintiffs’ medical experts explain that Bair Hugger increases the risk of DJI through two causal mechanisms—internal contamination and airflow disruption. Separately and independently, the mechanisms substantially increase the risk of DJI. Plaintiffs summarize each mechanism and some of supporting evidence as follows<sup>1</sup>:

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<sup>1</sup> One of the following slides summarizes Dr. Elghobashi’s LES CFD, which was peer-reviewed and recently published in the renowned *International Journal of Numerical Methods in Biomechanical Engineering*. *See* Dkt. 1813-30. 3M has never challenged Dr. Elghobashi’s qualifications or his methodology. For the first time in this MDL, however, 3M now claims that Dr. Elghobashi never “address[ed] the movement of squames with the Bair Hugger system turned off.” Dkt. 1719 at 15. Nonsense. Dr. Elghobashi performed his LES CFD in a model operating room with Bair Hugger turned off and then again changing only one input: he turned Bair Hugger on to determine what impact, if any, this dirty device had on the movement of squame-sized particles. *See* Dkt. 1813-14; *see also* Dkt. 1813-30.

# Bair Hugger is Contaminated

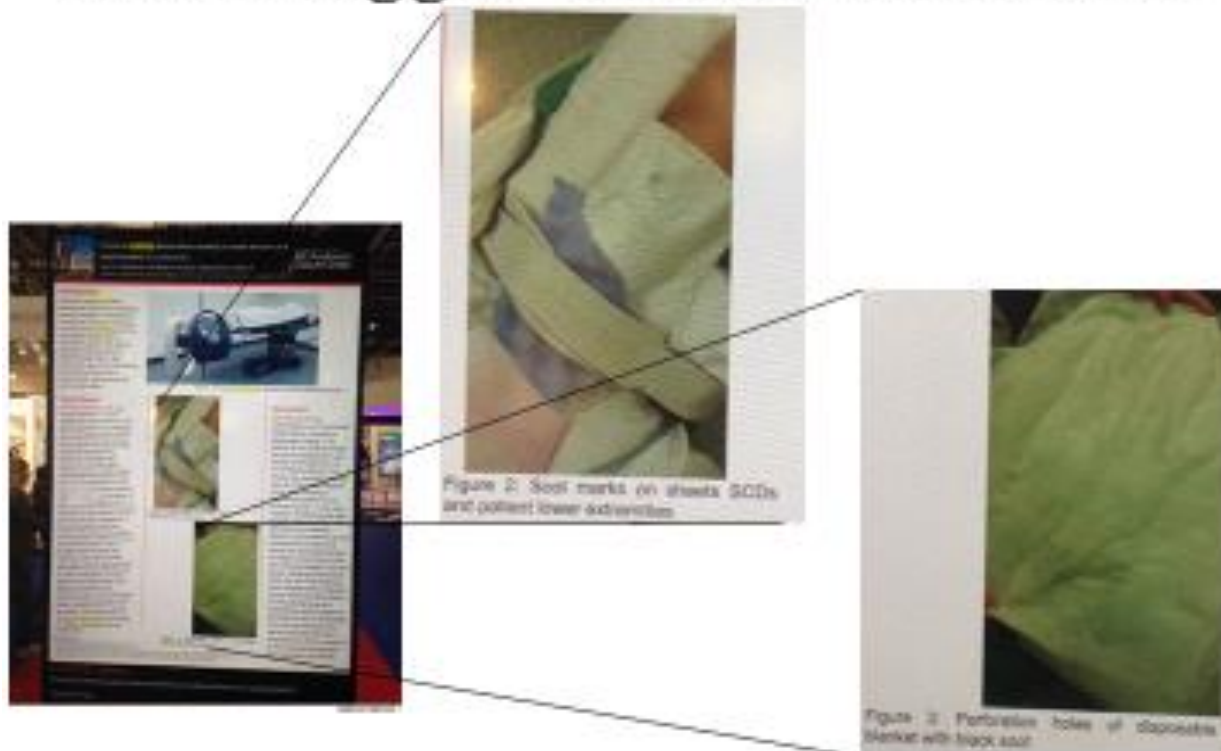


## The Bair Hugger Is Contaminated With Bacteria Inside The Blower And In The Hose

- Deposition of Al Van Duren, 3M 30(b)(6), March 7, 2017, 291:10-22 (PX5)
- [REDACTED]  
3MBH00005608 [REDACTED]
- Avidan M., et al., "CONVENTION WARMERS – NOT JUST HOT AIR" 52 Anesthesia 1073 (1997) (SJ DX64)
- 3MBH0025006-08 [REDACTED]  
[REDACTED] (PX78)



# Bair Hugger is Contaminated

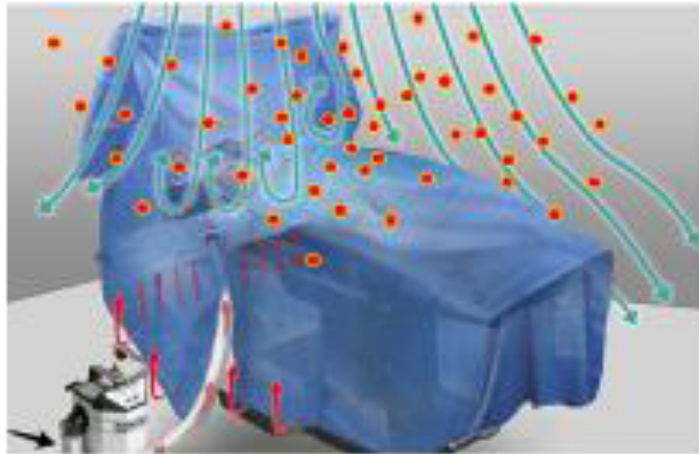


## Internal Contamination Inside The Bair Hugger Creates Emissions Risk

- SMBH01963525 (M.D. Anderson Hospital case report showing soot traveled through Bair Hugger machine, through blanket, on to patient) (PX76)
- Tsai 2017 (reporting that Bair Hugger filter did not prohibit "black soot" from reaching patient and declaring that "[d]ocumented complications from FAW use include an increased incidence of surgical site infections") (PX77)
- Deposition of Al Van Duren, 3M 30(B)(6), March 7, 2017 ("no reason to blow particulates into [the] blanket, which might end up leaving the blanket")
- Albrecht I, Albrecht II, and Reed (2013) (demonstrating that Bair Hugger emits "microbial contaminants into the OR")
- Bernards (PX14 at 1003-04) (BH was contaminated and associated with infection outbreak)
- ECRI (PX8) and Gjolaj 09 (PX7) (recognizing emission risk)
- Baker 2002 (PX5 – Dkt. 1813-4) (blanket is not designed to act as a filter)
- Michael Buck Report (demonstrating particles leaving the blanket)



## Bair Hugger Increases Particles Near Incision Site



### **Bair Hugger Increases The Particle Count Near Incision Site**

- Deposition of Al Van Duren, 3M 30(b)(6), March 7, 2017, 258:5-13 (PX4)
- He, X., et al., EFFECT OF HEATED-AIR BLANKET ON THE DISPERSION OF SQUAMES IN AN OPERATING ROOM, Int. J. Numer. Meth Biomed Engng. 2018 e2960 (Elghobashi peer-reviewed publication)(PX36)
- Legg I (PX21)
- Legg II (PX22)
- Desari (PX24)
- McGovern (PX25)
- Dkt. 950-14 (PX18 to Pl. Opp. to SJ ) (3M00580475 [REDACTED])

## CFD Establishes Particle Count Near Incision Site

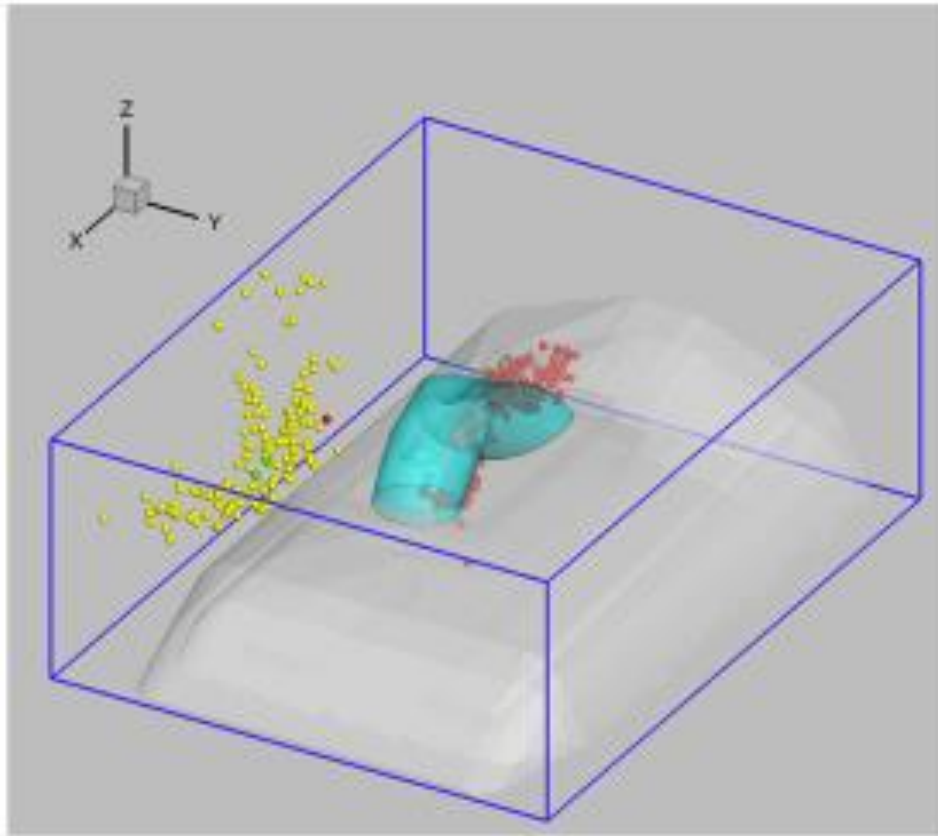
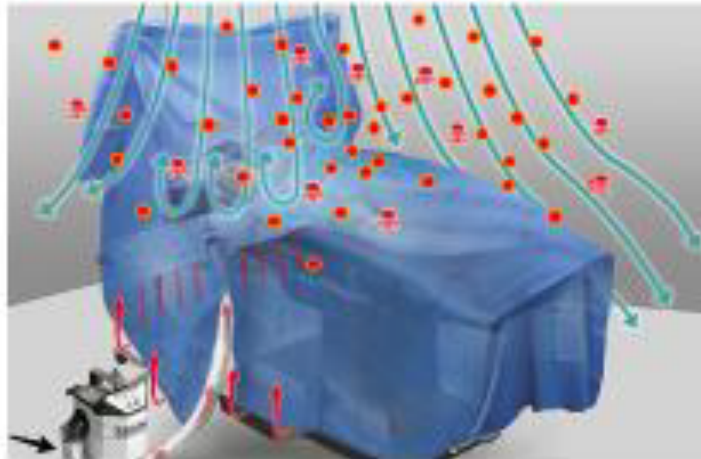


Figure 28: Zoom-in showing the instantaneous snapshot of squames near the surgical site at  $t = 27s$ .

### **Bair Hugger Increases The Particle Count Near Incision Site**

- Dr. Elghobashi's expert report and testimony established a conservative calculation of approximately 120 particles capable of carrying bacteria near the incision site caused by Bair Hugger (PX19)
- *See also* He, X., et al., EFFECT OF HEATED-AIR BLANKET ON THE DISPERSION OF SQUAMES IN AN OPERATING ROOM, Int. J. Numer. Meth Biomed Engng. 2018 e2960 (Elghobashi peer-reviewed publication) (PX36)

# Particles Carry Bacteria



## Particles Are Carriers For Infection-Causing Bacteria

- Deposition of 3M expert Richard Wenzel at 50:2-15 (testifying that perhaps 40% of operating room particles carry bacteria) (PX4)
- Darouiche (approximately 20% of particles carry CFUs) (PX38)
- ICOS Question 2 (2014) (advises reduction in airborne bacteria in operating room and monitoring of particulate count be used as real-time proxy for increased risk for wound contamination or infection) (PX58)

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Dkt. 950-12 (PX15 to Opp. to SJ

# Bacteria Cause Deep Joint Infection

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CONCLUSIONS AND RECOMMENDATIONS

### Association of Airborne Microorganisms in the Operating Room With Implant Infections: A Randomized Controlled Trial

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Francine Kovacs, MD<sup>5</sup> Carlos F. Reddy, MD<sup>6</sup> Daniel P. O'Connor, PhD<sup>7</sup>

## CFU and Particulate Densities and Infection

CFU density at incision sites was significantly related to incidence of implant infection ( $P=.021$ ), but not of incisional infection ( $P=.687$ ). Every 10 CFU/m<sup>3</sup> increase in median CFU density approximately doubled the probability of implant infection (Figure 4). CFU density was positively related to total particulate density ( $P<.001$ ) in the control group, indicating that airborne particle counts may be used as a proxy for ambient CFU density. No association between particle density

cause too. The primary source of these airborne microorganisms is the people in the operating room, such that the number of people, door openings, and room traffic all increase the quantity of airborne colony-forming units (CFUs).<sup>10-12</sup>

has indicated whether the density of airborne CPU measured at incinerator sites is related to increased incidence of SGA. Thus, the purpose of this study was to evaluate whether airborne CPU densities at the incinerator sites during operations is related to

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**Keywords:** child sexual abuse; disclosure; social support

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2. *Plaintiffs’ Medical Experts Have Also Used Reliable Scientific Methodologies in Opining that Bair Hugger Has In Fact Caused DJI.*

To the extent the Court’s question focuses on specific causation even though 3M has moved for reconsideration of the Court’s ruling on general causation, the inquiry is *fact-specific* and dependent on *each* plaintiff’s medical history, exposure, and treatment. *Gareis* is instructive. As explained below, Drs. Jarvis and Stonnington used differential diagnosis or etiology to “rule in” all plausible causes of DJI and then “rule out” all but the most likely cause of the plaintiff’s DJI. Their opinions are admissible under Eighth Circuit law. After all, 3M previously conceded that differential diagnosis is a valid method for determining specific causation “if general causation exists and a substantial proportion of competing causes are known.” *See Gareis*, Dkt. 35 at 14 (citing *Reference Manual* at 618).

a. *Differential diagnosis is a generally accepted methodology for determining whether Bair Hugger specifically caused DJI in an individual plaintiff.*

The Eighth Circuit endorses differential diagnosis as a valid methodology that experts routinely use for assessing specific causation. *See, e.g., Turner*, 229 F.3d at 1208. Because a differential diagnosis is “presumptively admissible,” a district court may not exclude such testimony unless the diagnosis is fundamentally unsupported. *See Glastetter v. Novartis Pharms. Corp.*, 252 F.3d 986, 989 (8th Cir. 2001). To perform a differential diagnosis, the expert “rules in” all plausible causes of the injury and then “rules out” the least plausible causes until the most likely cause of the plaintiff’s injury remains. *Id.* The expert then concludes that the defendant’s product caused or did not cause the injury. *Id.*

An expert is not required to rule out all possible causes in performing a differential diagnosis. *Johnson v. Mead Johnson & Co., LLC*, 754 F.3d 557, 563–64 (8th Cir. 2014). Likewise, a differential diagnosis should not be excluded if it is based on less than complete information. *Id.* The opinion is admissible if the expert rules out obvious alternative causes and explains why other conceivable causes are excludable. *Lauzon v. Senco Prods.*, 270 F.3d 681, 693–94 (8th Cir. 2001). To hold otherwise denigrates *Daubert*’s admonition that challenges to the basis of an expert’s opinion should be tested by the adversary process. *Id.*

In addition, Rule 702 and *Daubert* do not require an expert to express a differential diagnosis opinion to a high level of scientific certainty in order for the opinion to be admissible. *Kudabeck v. Kroger Co.*, 338 F.3d 856, 861–62 (8th Cir. 2003). Flaws in the diagnosis go to the weight of the testimony, not its admissibility. *Johnson*, 754 F.3d at 564; *see also Hill v. Southwestern Energy Co.*, 858 F.3d 481, 486 (8th Cir. 2017) (stating that a “crude and imperfect” analysis does not render an opinion unreliable and that mere disagreement with an expert’s assumptions and methodology does not warrant exclusion). So long as the testimony falls within “the range where experts might reasonably differ,” the jury, not the trial court, should choose among conflicting views of the opposing experts. *Johnson*, 754 F.3d at 564 (citing *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 153 (1999)).

Thus, while it is common for medical experts to disagree on causation conclusions from a differential diagnosis, “questions of conflicting evidence must be left for the jury’s determination.” *See Hose v. Chicago Nw. Transp. Co.*, 70 F.3d 968, 976 (8th Cir. 1995).



- b. *In Gareis, Drs. Jarvis and Stonnington conducted a differential diagnosis to eliminate alternative causes of Mr. Gareis's DJI and identified Bair Hugger as the most probable cause of DJI.*

In describing their differential diagnoses in *Gareis* and other bellwether cases, Drs. Jarvis and Stonnington explained that they considered all of the relevant scientific evidence—including published medical literature, the patient's medical records, and deposition testimony of OR staff—to rule in scientifically plausible causes and to rule out less likely potential causes in concluding that Bair Hugger was the “most probable” cause of DJI. *See, e.g., Gareis*, Dkt. 60 (Jarvis Rpt. at 7–11); Dkt. 61 (Stonnington Rpt. at 3–7).

Although contamination of the operating room air is not the only cause of DJI, it is the most common and serious cause of it—a fact strongly supported in the medical literature. In contrast, there are no “idiopathic” or unknown causes of DJI. The experts for both Mr. Gareis and 3M therefore agreed that DJI does not occur without bacteria and that the bacteria that inoculated Mr. Gareis's DJI arose from one of several known potential sources. *See, e.g., id.*, Dkt. 60 (Jarvis Rpt. at 7–9); Dkt. 61 (Stonnington Rpt. at 2–4). As explained in Section III, moreover, Drs. Jarvis and Stonnington had more than enough scientific evidence to rule in Bair Hugger as the leading cause of airborne contamination.<sup>2</sup>

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<sup>2</sup> Aside from the body of published and peer-reviewed studies showing that Bair Hugger contaminates the sterile field, Dr. Jarvis noted that the McGovern study reported that Bair Hugger more than doubles the risk of DJI. Statistically, this finding suggests that Bair Hugger was the most likely cause of Mr. Gareis's DJI and thus provides an *alternative, independent* basis to rule in Bair Hugger as a leading cause of DJI. *See Gareis*, Dkt. 60 (Jarvis Rpt. at 10–12). Indeed, Dr. Jarvis and 3M's expert agree that “[i]f the incidence of disease in an exposed group is more than twice the incidence in the unexposed group, the probability that exposure to the agent in a similarly situated individual is also greater than 50%.” *Id.* at 10 n.8 (citing Holford Dep. at 225:19-226:1 and *Reference Manual* at 612).

Besides Bair Hugger, Drs. Jarvis and Stonnington ruled in the following plausible causes of Mr. Gareis's DJI: (1) HVAC system; (2) patient's own flora; (3) surgical team contamination; (4) surgical procedure and technique; and (5) break in the sterile field. *See id.*, Dkt. 60 (Jarvis Rpt. at 7–11); Dkt. 61 (Stonnington Rpt. at 2–4). Notably, 3M's experts agreed on most of the same alternative causes of DJI. Like 3M's experts, Drs. Jarvis and Stonnington also accounted for Mr. Gareis's risk factors, which do not cause infections but may have made him more susceptible to DJI. *See, e.g., id.*, Dkt. 60 (Jarvis Rpt. at 6–7).

Drs. Jarvis and Stonnington then considered these causes and systematically ruled out the less likely causes based on their review of the relevant data. *Id.*, Dkt. 60 (Jarvis Rpt. at 8–10); Dkt. 61 (Stonnington Rpt. at 3–4). They also considered other potential but less plausible causes of Mr. Gareis's DJI put forth by 3M and explained why they ruled out those factors too. *See id.*, Dkt. 58 at 9, 26–29 (ruling out skin lesion removal, endogenous inoculation after wound closure, change in wound dressing, glove tears, movement of OR staff, surgical equipment, other heat sources, and direct migration of bacteria). Significantly, 3M's experts either ruled out most of these “alternative” causes or conceded that they were either irrelevant or unlikely to have caused Mr. Gareis's DJI. *Id.* at 30–32.

All told, Drs. Jarvis and Stonnington testified that Bair Hugger was the most likely cause of bacteria entering the sterile field and inoculating Mr. Gareis's hip implant, after identifying and then ruling out other less likely causes of DJI. This is a reliable differential diagnosis methodology, as the Court correctly concluded in denying 3M's case-specific

*Daubert* motions in *Gareis*.<sup>3</sup> See, e.g., *Kudabeck*, 338 F.3d at 862; *In re Prempro Prods. Liab. Litig.*, 586 F.3d 547, 566 (8th Cir. 2009) (the existence of multiple potential causes does not invalidate a differential diagnosis where the expert addresses other potential causes); *Lauzon*, 270 F.3d at 693–94 (failure to account for all hypothetical causes is not grounds for exclusion); *Johnson*, 754 F.3d at 564 (criticisms of a diagnosis go to the jury).

## **II. The Jeans Study Does Not “Suggest” that MSSA Screening Confounded the McGovern Study and Thus Does Not Impact Dr. Samet’s Opinion or the MDL**

The Court’s second question involves the Jeans study, which “observed a significant decrease in the MSSA infection rate—predominately in the hip replacement group—after the introduction of the MSSA screening program.”<sup>4</sup> Dkt. 1905 at 2. Given that observation, the Court has posed the following question: “How do these findings, which suggest that MSSA screening confounded the McGovern Observational Study (2011), impact Dr. Samet’s opinion that the Bair Hugger device constitutes a substantial contributing cause?” *Id.* In addition, the Court questions the relevance of these findings to the hip and knee surgeries in the MDL as well as how many cases involve hip and knee arthroplasties. *Id.*

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<sup>3</sup> Drs. Jarvis and Stonnington used the same methods in opining about specific causation in *Axline* and *Trombley*, e.g., MDL Dkt. 1792, but *Gareis* is the only bellwether in which this Court rendered a *Daubert* decision on their differential diagnoses. Final judgment was entered in *Gareis* on October 29, 2018, Dkt. 520, and the case is now pending on appeal. This Court therefore lacks jurisdiction to reconsider its case-specific ruling. Regardless, the specific causation opinions of Drs. Jarvis and Stonnington in *Gareis*, *Axline*, and *Trombley* are irrelevant as 3M’s motion relates to *general causation*, not *specific causation*.

<sup>4</sup> Notably, the Court did not specify the type of “infection” that decreased from MSSA screening, even though this MDL and the McGovern study encompass only DJI. Dkt. 1905.

**A. The Jeans Study Does Not “Suggest” that MSSA Screening Confounded the McGovern Study Because the Studies Analyzed Different Outcomes.**

As a threshold matter, the Jeans study does not “suggest” that MSSA screening confounded the McGovern study; it “suggests that screening and decolonisation was responsible [for the reduction] in MSSA SSI,” which includes both “deep *and* superficial infection.” Dkt. 1813-43 at 5 (Jeans study at 4) (emphasis added); *id.* at 4 (Jeans study at 3) (defining “PJI” as “deep and superficial infection”). The McGovern study, unlike the Jeans study, did not analyze both “deep *and* superficial infection.” *Id.* (emphasis added). That published and peer-reviewed study focused solely on DJI—the subset of surgical site infections at issue in this litigation. *See, e.g.*, Dkt. 1813-41 at 3 (Holford Dep. at 96:17-20).

The difference between “DJI” as used in the McGovern study and “SSI” or “PJI” as used in the Jeans study is not mere word play. Every expert in this case, including 3M’s epidemiologists, agrees that it is not “fair” to compare “deep joint infections” to “[o]ther types of infections,” even if the infection involves MSSA. Dkt. 1813-37 at 9 (Borak Dep. at 201–202); Dkt. 1813-41 at 13 (Holford Dep. at 306–308) (similar); *see also* Dkt. 1813-1 at 6–9, 17–18 (Jarvis Rpt. at 6–8, 15–17) (discussing differing etiology of DJI and SSI).

Because the Jeans study did not independently analyze the impact of MSSA screening on “superficial *or* deep SSIs,” there is no scientific basis to “suggest” that MSSA screening confounded the McGovern study. *See* Dkt. 1792 at 16 (Jarvis *Trombley* Rpt. at 15) (refusing to rely on Jeans because “there was no stratification of the data by superficial or deep SSIs”); *see also* PX75 (Jarvis Aff. ¶¶ 2–3(a)-(n)) (providing nine additional reasons that “the Jeans Study does not ‘suggest’ that MSSA screening confounded the McGovern

study”). In fact, 3M’s epidemiologist *admitted* so at his deposition, leaving 3M without any scientific evidence that MSSA screening actually impacted the DJI rates in McGovern:

**Q:** [Y]ou’ve mentioned before that the Jeans study deals with both deep joint and superficial wound infections; correct?

**A:** That’s correct.

**Q:** Do you know if there was a change . . . in the deep joint infections rates in the Jeans study?

**A:** One can’t specifically determine that.

**Q:** So according to the Jeans study you can’t determine if there was a change in the deep joint infection rates between the pre-screening group and the post-screening group, correct?

**A:** I don’t have data on the deep joint infection rate in either of those time periods.

**Q:** So you can’t determine if there was a reduction . . . in the deep joint infection rates as a result of the MSSA screening protocol; correct?

**A:** Yes. Nor did I ever suggest that there was.

*See, e.g.,* Dkt. 1813-42 at 6 (Borak Dep. II at 35:21-36:14) (emphasis added).

Given that limitation and the other flaws of the Jeans study,<sup>5</sup> it is unsurprising that coauthor Dr. Reed continues to cite McGovern for the proposition that forced-air warming devices are “associated [with] substantially *higher rates of post-operative infection*,”

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<sup>5</sup> As explained in Plaintiffs’ opposition to 3M’s motion for reconsideration, these flaws include: (1) no set protocol prior to MSSA screening; (2) Hawthorne Effect; (3) failure to track use of MSSA cleansing products; (4) failure to identify existence of MSSA prior to use of cleansing products; (5) failure to confirm eradication of MSSA after use of cleansing products; and (6) incomplete pre-screening and follow-up data on infection rates. *See* Dkt. 1813-43 at 3–5 (Jeans study at 2–4); *see also* Dkt. 1786 at 36–43. For numerous other reasons, Dr. Jarvis’s Affidavit likewise concludes that “the Jeans Study does not ‘suggest’ that MSSA screening confounded the McGovern study.” *See* PX75 (Jarvis Aff. ¶3(a)-(n)).

despite Jeans. Dkt. 1813-44 at 7 (Reed 2019 at 7) (emphasis added). He also continues to recommend using “a resistive heating mattress or blanket over a forced-air warming device” such as Bair Hugger for the same reason.<sup>6</sup> *See id.* at 6, Table II; *see also* Dkt. 1813-42 at 6 (Borak Dep. II at 35:13) (admitting that Bair Hugger may have confounded Jeans).<sup>7</sup>

**B. The Jeans Study Does Not Change Dr. Samet’s Expert Opinion that Bair Hugger is a “Substantial Contributing Cause” of Deep Joint Infection.**

Although the Jeans study does not change Dr. Samet’s expert opinion that Bair Hugger is a “substantial contributing cause” of DJI, *see, e.g.*, Dkt. 1813-2 at 18, Plaintiffs did not attach his supplemental affidavit to their prior submission for three simple reasons.

*First*, Plaintiffs have refrained from filing supplemental reports from Dr. Samet or any other expert given the Court’s November 6, 2018 Order striking Dr. David’s and Dr. Bushnell’s supplemental general causation reports. *See* Dkt. 1580 at 2. Mindful of that

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<sup>6</sup> 3M’s reply brief falsely asserts that “[n]o such recommendation can be found” in the 2019 Reed study, Dkt. 1849 at 15 n.4, despite the plain language of Table II of that study. *See* Dkt. 1813-44 at 7 (Reed 2019 at 7). 3M’s reply also states that the “paper briefly discusses teh [sic] Observational study,” admitting that Bair Hugger “may be an explanatory factor in the changed fortunes of LAF [laminar flow],” Dkt. 1849 at 15 n.4, but ignoring Dr. Reed’s additional statement that forced-air warming is “associated with substantially higher numbers of simulated particles over the sterile field and substantially higher rates of post-operative [infection].” Dkt. 1813-44 at 7 (Reed 2019 at 7) (citing McGovern 2011).

<sup>7</sup> 3M’s argument that Plaintiffs’ “attacks on Jeans apply equally to the observational study” makes no sense. *Cf.* Dkt. 1849 at 11–13. Unlike 3M’s claim that Jeans “proves” that MSSA screening reduces SSI, *see* Dkt. 1719 at 26, Plaintiffs have never argued that McGovern *ipso facto* proves that Bair Hugger causes DJI. 3M’s conflation of “proof of causation” with “causal inference” only highlights its ongoing confusion of the statistical concept of “association” with the epidemiological concept of “causation”—a judgment scientists make after considering epidemiological data together with *other scientific evidence*. *See Reference Manual* at 598 (“Epidemiology cannot prove causation; rather causation is a judgment for epidemiologists and others.”); *cf.* Dkt. 1849 at 15 (incorrectly asserting that if an association “does not prove causation,” then “no causation inference can be drawn”).



Order, Plaintiffs “requested leave of Court to conduct additional discovery related to Defendants’ motion for reconsideration.” Dkt. 1747 at 1. Specifically, Plaintiffs sought leave to depose the authors of the Jeans study and to supplement the reports of “Drs. Jarvis, Samet, and Stonnington” given 3M’s “reliance on the same in moving to exclude their expert opinions.” *Id.* at 2. Magistrate Judge Shultz, however, denied Plaintiffs’ request. *See* Dkt. 1781 at 1. Plaintiffs therefore determined that they were precluded from filing supplemental expert reports on general causation. Misleadingly, 3M avoided mentioning any of the foregoing Orders in claiming that “Plaintiffs offer no response from Dr. Samet . . . to Dr. Borak’s opinion on the significance of the Jeans study.” Dkt. No. 1849 at 2, 16.

*Second*, Plaintiffs stated in their reconsideration briefing that Dr. Samet’s general causation report *already* provides sound reason to reject 3M’s reliance on Jeans. Dkt. 1786 at 40–41. There, Dr. Samet explained that “[a] more general argument against confounding can also be made [based on] the magnitude of the association (3.8 odds ratio) reported by McGovern.” Dkt. 1813-2 at 13. “For the sole explanation to lie with confounding,” he said, “there would need to be sufficient positive confounding [by another variable] to explain the association fully.” *Id.* Applying that rationale here, Jeans does not “suggest” that McGovern was confounded by MSSA screening. Dkt. 1719 at 29–32. McGovern reported an “elevated infection odds ratio of 3.8,” Dkt. 1813-20 at 1, while the odds ratio in Jeans is only 1.37—less than half the effect from using air-free warming instead of Bair Hugger.<sup>8</sup>

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<sup>8</sup> The 3.8 odds ratio actually underestimates the Bair Hugger’s risk given the admission of 3M’s epidemiologist that the change in antibiotic caused negative, not positive, confounding. *See* Dkt. 1813-41 at 15 (Holford Dep. at 317:2–6) (“reverse confounding”).

Because the risk of infection remains above 2.0 (*i.e.*,  $3.8 - 1.37 = 2.43$ ) even if the reduction in “PJI” reported in the Jeans study is incorrectly presumed to be due entirely to the initiation of MSSA screening rather than “other factors” like air-free warming, *see* Dkt. 1813-43 at 5, this calculation alone dooms 3M’s argument. *See, e.g., In re Viagra Prods. Liab. Litig.*, 572 F. Supp. 2d 1071, 1078 (D. Minn. 2008) (citing *Reference Manual* at 384); *Manko v. United States*, 636 F. Supp. 1419, 1434 (W.D. Mo. 1986) (“A relative risk greater than ‘2’ means that the disease more likely than not was caused by the event.”), *aff’d*, 830 F.2d 831 (8th Cir. 1987); *Liab. v. Sec’y of Health & Human Servs.*, 2000 WL 1517672, at \*15 (Fed. Cl. Sept. 7, 2000) (collecting appellate cases regarding the doubling of risk).

*Third*, Dr. Borak’s recent deposition testimony eliminates any need for Dr. Samet to file a supplemental report regarding the Jean study. In his expert report in *Axline*, which 3M cited in moving for reconsideration of general causation, Dr. Borak summarily opined that Jeans “confirms that adoption of MSSA screening almost exclusively for patients using the non-BH warmer confounded the results of the McGovern study.” Dkt. 1720-1 at 181. At his deposition, though, Dr. Borak reversed course, confessing that Jeans “*does not prove causation*” with respect to MSSA screening and its relationship with MSSA infections; nor does it “suggest,” let alone confirm, confounding of the DJI rates reported in McGovern. *See, e.g.*, Dkt. 1813-42 at 3, 6 (Borak Dep. II at 13:2–25, 36:10–14). In fact, Dr. Borak suggested that *Bair Hugger* was a “*confounder*” of the Jeans study. *E.g., id.* at 6 (Borak Dep. II at 36:10–13). Since Dr. Borak’s own testimony defeats 3M’s reliance on the Jeans study, a supplemental affidavit from Dr. Samet would only add icing to the proverbial cake.

Out of abundance of caution and pursuant to the Court’s express instruction, however, Plaintiffs have attached Dr. Samet’s supplemental affidavit to this Memorandum. *See* Dkt. 1905 at 2 (requesting Dr. Samet’s opinion on the impact, if any, of the Jeans study on his general causation opinion). Dr. Samet’s affidavit makes clear that the Jeans study does not change his opinion that Bair Hugger is a substantial contributing cause of DJI. PX74 at 1–2. Indeed, Dr. Samet reiterates the same point he made in his first report: MSSA screening cannot confound the 3.8 odds ratio of McGovern because, even assuming MSSA screening impacts DJI, it has a “smaller effect.” *Id.* at ¶3. Additionally, MSSA screening occurred in *both arms* of the McGovern study—not just the air-free period—thus reducing the likelihood that the difference in DJI rates was due to MSSA screening. *Id.* Not to mention that Jeans analyzed “both deep *and* superficial infections,” whereas McGovern analyzed only the former. *Id.* ¶2 (emphasis added). As a result, “the relevance of the Jeans et al. study is uncertain as deep joint infections were not separately analyzed.” *Id.* ¶3. Like Dr. Jarvis, Dr. Samet therefore concludes that “this additional study does *not* change [his] opinion . . . that the Bair Hugger device would constitute a *substantial contributing cause of deep joint infection*.” *Id.* ¶4 (emphasis added); *see also* PX75 (Jarvis Aff. ¶2) (“[T]he Jeans Study does not ‘suggest’ that MSSA screening confounded the McGovern study.”).

**C. The Jeans Study is Not Relevant to the Hip or Knee Cases in the MDL Because its Findings Do Not Exclusively Pertain to Deep Joint Infection.**

As stated in Dr. Samet’s supplemental affidavit as well as Plaintiffs’ opposition to 3M’s motion for reconsideration—and as Dr. Borak readily admitted at his deposition—the Jeans study is not relevant to the hip or knee cases in this MDL proceeding. The Jeans

study reported that “[t]he MSSA screening and eradication protocol used in our institution was effective at reducing rates of MSSA PJI,” Dkt. 1813-43 at 2, which the authors explicitly defined as both “deep *and* superficial infection.” *Id.* at 4 (emphasis added); *id.* (“A multivariate logistic regression model for predictors of MSSA PJI (including deep *and* superficial infection) was constructed.”) (emphasis added). The hip and knee cases in this MDL proceeding, however, involve solely DJI. *See, e.g.*, Dkt. 1813-2 at 17 (Samet Rpt. at 16) (“In my judgment, the full body of evidence is sufficient to conclude that the Bair Hugger device causally increases risk for *deep joint infection*.”) (emphasis added). Indeed, *none* of the bellwether cases to date have involved superficial, wound, or tissue infections.

Given that dichotomy, experts on both sides agree that the findings of Jeans do not address whether MSSA screening reduces DJI—the outcome at issue in this proceeding. 3M’s epidemiologist testified that he could neither “determine” nor “suggest” if MSSA screening reduced DJI. *See* Dkt. 1813-42 at 6 (Q: So you can’t determine if there was a reduction . . . in the deep joint infection rates as a result of the MSSA screening protocol; correct? A: Yes. *Nor did I ever suggest that there was.*). Dr. Jarvis likewise refused to rule in MSSA screening as a potential cause of DJI because “there was *no stratification* of the data by superficial or deep SSIs.” Dkt. 1792 at 16. Even Dr. Reed—coauthor of Jeans and McGovern—did not cite the former study in his more recent article stating that Bair Hugger

is “associated [with] substantially higher rates of post-operative infection.” Dkt. 1813-44 at 7.<sup>9</sup> Thus, the Jeans study is not relevant to any knee *or* hip case in this MDL proceeding.<sup>10</sup>

Finally, even if Jeans did “suggest” that MSSA screening reduces DJI, it would *still* be an abuse of discretion to exclude McGovern. Jeans does not address the relevant exposure (Bair Hugger) or outcome (DJI). *See, e.g., General Elec. Co. v. Joiner*, 522 U.S. 136, 144–45 (1997) (rejecting expert’s reliance on studies because they were “so dissimilar to the facts presented in this litigation”). Nor has 3M cited a *single epidemiologic study* finding that Bair Hugger does *not* increase DJI. The published and peer-reviewed McGovern study thus remains admissible evidence of causation despite hypothetical confounding, as this Court knows from its *Daubert* order in this and other cases. *See* Dkt. 1024 at 9 (“Samet need not rule out every alternative explanation for the observed hospital’s drop-off in infections.”); *Johnson*, 754 F.3d at 564 (reversing this Court’s prior *Daubert* order because expert’s failure to consider potential confounders did not undermine the expert testimony; rather, it was up to the jury to evaluate the veracity of the testimony).<sup>11</sup>

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<sup>9</sup> As explained in Plaintiffs’ prior brief, elementary statistical calculations *prove* that MSSA screening does not affect DJI rates. *See* Dkt. 1786 at 37 (“[W]hen the McGovern data are removed from the amalgamated data set of Jeans, the significance of the association disappears ( $p=0.9$ ) because the infection rate in each arm of the study is identical (1.4%).”).

<sup>10</sup> Plaintiffs sought leave to depose Jeans et al. in order to determine whether the study’s raw data differentiates between infections, *but the request was denied*. *See* Dkt. 1781 at 1.

<sup>11</sup> It is blackletter law in mass tort cases that “vigorous cross-examination and presentation of contrary evidence are the appropriate means of attacking [a] [s]tudy’s limitations,” which include potential confounding. *In re Abilify Prod. Liab. Litig.*, 299 F. Supp. 3d 1291, 1325 (N.D. Fla. 2018); *In re Lipitor Mktg., Sales Practices & Prod. Liab. Litig.*, 174 F. Supp. 3d 911, 921 (D.S.C. 2016); *In re Orthopedic Bone Screw Prod. Liab. Litig.*, No. 1014, 1997 WL 230818, at \*8 (E.D. Pa. May 5, 1997); *see also Quiet Technology DC-8*,

**D. Thousands of Hip and Knee Cases Have Been Filed in this MDL.**

The Court's next question regarding the Jeans study pertains to the number of hip and knee cases that have been filed in this proceeding. To date, Plaintiffs have filed approximately 1,700 hip cases and 3,100 knee cases in this MDL. Zimmerman Decl. ¶2.

**III. The Published and Peer-Reviewed McGovern Study is Part of the Totality of Evidence that Supports Plaintiffs' Theories of General and Specific Causation**

The Court's final question involves the McGovern study. Dkt. 1905 at 2. Given Dr. Samet's testimony that McGovern provides the only "estimate of the risk" regarding the association between Bair Hugger and DJI, the Court queries: "[I]f the Court finds that [the study] does not reliably support the allegations involving hip surgeries, what evidence could Plaintiffs rely on to establish that the Bair Hugger was the source of infection?" *Id.*

**A. The McGovern Study Provides Reliable Mechanistic and Statistical Support for a Relationship Between Bair Hugger and DJI in Hip Cases.**

The Court's question regarding additional causal evidence depends on its presumption that McGovern "does not reliably support the allegations involving hip surgeries." *Id.* That presumption, in turn, appears to depend on Jeans given the Court's focus on "hip surgeries." *Id.* As explained, excluding McGovern based on Jeans would be blatant error under any standard. *E.g., Johnson* 754 F.3d at 564. Even if the reduction in

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*Inc. v. Hurel-Dubois UK Ltd.*, 326 F.3d 1333, 1345 (11th Cir. 2003) ("[O]bjections to the inadequacies of a study are more appropriately considered an objection going to the weight of the evidence rather than its admissibility.") (quoting *Hemmings v. Tidyman*, 285 F.3d 1174, 1188 (9th Cir. 2002)); *In re Seroquel Prod. Liab. Litig.*, No. 6:06-MD-1769-ORL, 2009 WL 3806435, at \*8 (M.D. Fla. June 23, 2009) ("Any alleged flaws in the individual studies upon which [the expert] relied, such as failure to control for various diabetes risk factors, go to the weight of the evidence, not the validity of [the expert's] methods.").



“PJI” reported in Jeans could be solely attributed to MSSA screening—which it cannot based on Dr. Borak’s contrary testimony regarding DJI rates and his admission that Bair Hugger may have instead caused the effect—McGovern would *still* support causation in hip cases. Dkt. 1786 at 40–42; Dkt. 1813-42 at 6 (Borak Dep. II at 35:21-36:14). In fact, the “odds of infection associated with *hip replacement [are] 4.1 times greater* than the odds for knee replacement” with Bair Hugger. Dkt. 1813-20 at 7–8 (McGovern at 1542).

What’s more, McGovern did not just report an “estimate of the risk,” as stated by the Court; it reports a *statistically significant association* between Bair Hugger and DJI. Dkt. 1813-20 at 2 (McGovern at 1537) (p=0.024); *see also Reference Manual* at 573 (odds ratios show the “magnitude of [an] association” but “say nothing” about the “statistical significance” of it). Thus, whether or not McGovern supplies the only estimate of risk, its findings are “unlikely to be the result of random error,” as confirmed by *post-publication data*.<sup>12</sup> *See Reference Manual* at 573 (“A study that is statistically significant has results that are unlikely to be the result of random error.”); Dkt. 1813-2 at 12–13 (Samet Rpt. at 11) (“[A]dditional data collected after publication of the McGovern study continued to demonstrate [a] ratio very similar to the 3.8 odds ratio reported in the published study.”).<sup>13</sup>

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<sup>12</sup> Plaintiffs are unaware of any authority holding that an expert’s general causation opinion must be supported by multiple epidemiologic studies, especially where, as here, there are no properly powered studies showing a lack of association between Bair Hugger and DJI.

<sup>13</sup> Even if Jeans somehow vitiated the statistical significance of McGovern’s findings, despite the fact that Jeans did not independently analyze the same variables or outcome, it would still be error to exclude the McGovern study. *E.g., In re Viagra Prod. Liab.*, 572 F. Supp. 2d 1071, 1081 (D. Minn. 2008) (“There is persuasive authority stating that on a *Daubert* motion involving general-causation evidence in an MDL matter, lack of statistical

Nor does Jeans discuss, much less rebut, the *independent mechanistic evidence* provided in McGovern. Besides analyzing DJI data before and after discontinuation of Bair Hugger, the well-credentialed authors demonstrated how Bair Hugger increases DJI in *hip replacement procedures*. See Dkt. 1813-20 at 3 (McGovern at 1538). They found that Bair Hugger “mobilized under-drape air so that it passed over the anesthesia/surgery drape and into the surgical site, but conductive fabric warming did not have a mobilizing effect.” *Id.* at 5. Because these findings provide “strong evidence that use of forced-air warming, compared with conductive-fabric warming, increase[s] [particle] counts over the surgical site,” Dkt. 1813-2 at 16 (Samet Rpt. at 15), the authors concluded that such mechanistic evidence “offers a *plausible explanation* for the *significant association* between the patient warming device and the risk of SSI in this study.” Dkt. 1813-20 at 3 (McGovern at 1538).

In sum, McGovern provides reliable statistical *and* mechanistic evidence that Bair Hugger increases DJI. The study was peer-reviewed, published, contains known rates of error, and results from generally accepted scientific methods. It meets “the precise standards that the Supreme Court has signaled that the Court should consider when determining reliability.” *Viagra*, 572 F. Supp. 2d at 1081 (citing *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 592–95 (1993)). In addition, the published and peer-reviewed McGovern study is not just *any* evidence of causation but “good evidence” of it given the study’s “plausible explanation” for the statistically significant association between Bair Hugger and DJI. See, e.g., *In re Lipitor Prod. Liab. Litig.*, 174 F. Supp. 3d at 915 n.2 (citing

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significance . . . does not detract from the reliability of the study.”) (citing *In re Phenylpropanolamine Prod. Liab. Litig.*, 289 F. Supp. 2d 1230, 1241 (W.D. Wash. 2003)).

*Reference Manual* at 221 (“[O]bservational studies provide *good evidence* [when] [t]here is a plausible explanation for the effect of the independent variable.”) (emphasis added)).

Accordingly, McGovern’s “estimate of the risk” cannot be divorced from its un rebutted mechanistic evidence. *See* Dkt. 1813-13 at 4 (3M admits “every study shows that the Bair Hugger increases the absolute count of particles over the sterile field”). Nor can it be excluded from the totality of evidence. *See Reference Manual* at 20 (“[S]cientists do not review each scientific study individually for whether by itself it reliably supports the causal claim. . . . [They synthesize] data addressing different linkages [to form] a more complete causal evidence model [that] can provide the biological plausibility needed to establish the association.”). Doing so would lead to one (and only one) unfortunate result: an abuse of discretion under Rule 702. *See U.S. v. W.R. Grace*, 504 F.3d 745, 765 (9th Cir. 2007) (stating that district court erred in “conduct[ing] a document-by-document Rule 702 analysis that deconstructed the experts’ testimony in a manner not contemplated by Rule 702” and noting that “the study’s failure to establish causation goes to the weight it should be accorded”); *Block v. Woo Young Med. Co.*, 937 F. Supp. 2d 1028, 1040–41 (D. Minn. 2013) (Tunheim, J.) (“[C]ourts must look to the totality of evidence in determining whether an expert’s opinion is relevant and reliable.”) (citing, *e.g.*, *W.R. Grace*, 504 F.3d at 765).<sup>14</sup>

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<sup>14</sup> *Accord Milward v. Acuity Specialty Prods.*, 639 F.3d 11, 23 (1st Cir. 2011); *NutraSweet Co. v. X-L Eng’g Co.*, 227 F.3d 776, 789 (7th Cir. 2000); *In re Neurontin Sales and Mktg., Prod. Liab. Litig.*, 612 F. Supp. 2d 116, 140 (D. Mass. 2009); *In re Testosterone Replacement Therapy Prod. Liab. Litig.*, 2017 WL 1833173, at \*9 (N.D. Ill. May 8, 2017).

**B. In Addition to McGovern, Other Record Evidence Supports Plaintiffs’ Medical Experts’ Opinions regarding General and Specific Causation.**

Assuming, *arguendo*, that the Court excludes the McGovern study, dismissing any of the knee *or* hip cases involving DJI would constitute a further abuse of discretion. The general causation opinions of Drs. Jarvis and Stonnington do not depend on McGovern. Nor do their specific causation opinions require application of that peer-reviewed study.<sup>15</sup>

Tellingly, the same cases cited by 3M make clear that “a plaintiff need not introduce epidemiological evidence of causation in order to satisfy *Daubert*’s threshold for admission of expert medical testimony.” *Glastetter*, 252 F.3d at 992. While “epidemiological evidence might [assist Plaintiffs] in establishing causation,” its absence would “not doom” this case. *Id.* In other words, McGovern is *relevant but not required* evidence of causation given the multiple lines of evidence showing an established chain of infection. Dkt. 1813-36 at 3–4 (Samet Dep. at 165:6–9, 169:18–20) (relying on “different lines of evidence”).

Any contrary conclusion is “irreconcilable” with “the liberal admissibility standards of the federal rules and the express teachings of *Daubert* about the need for flexibility in the district court’s gate-keeping role.” *In re Ephedra Prod. Liab. Litig.*, 393 F. Supp. 2d 181, 188 (S.D.N.Y. 2005). For that reason, “no court has held that epidemiological evidence is necessary to establish general causation.” *In re Meridia Prods. Liab. Litig.*, 328 F. Supp. 2d 791, 801 (N.D. Ohio 2004); *Bonner*, 259 F.3d at 929 (there is “no requirement

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<sup>15</sup> The Court’s final question—like its first question—pertains to *specific causation*. See Dkt. 1905 at 2 (“[W]hat evidence could Plaintiffs rely on to *establish* that the Bair Hugger *was the source of infection*.”) (emphasis added). 3M, however, has moved for reconsideration of the Court’s ruling on *general causation*. See Dkt. 1718. Given this seeming conflict, Plaintiffs respectfully identify evidence of general *and* specific causation.

that published epidemiological studies supporting an expert's opinion exist in order for the opinion to be admissible"); *Kloss v. Wal-Mart Stores, Inc.*, 2013 WL 268936, at \*7 (D. Minn. Jan. 24, 2013) (same); *In re Heparin Prod. Liab. Litig.*, 803 F. Supp. 2d 712, 728 (N.D. Ohio 2011) (circuit survey showing that epidemiologic evidence is not necessary).<sup>16</sup>

To the extent 3M claims that the "*Reference Manual on Scientific Evidence* rejects any attempt to infer causation merely from application of the Bradford-Hill criteria in the absence of epidemiological studies finding an association," 3M forgets that Drs. Jarvis and Dr. Stonnington do *not* apply the Bradford Hill criteria or heavily rely on McGovern in opining about general *or* specific causation.<sup>17</sup> *Cf.* Dkt. 1719 at 28. The cases cited by 3M further acknowledge that requiring a medical expert to cite at least one "statistically significant epidemiological study as the beginning point for application of the Bradford Hill criteria does *not* require [the same expert] to have a statistically significant study in order to prove causation." *Dunn v. Sandoz Pharm. Corp.*, 275 F. Supp. 2d 672, 680 (M.D.N.C. 2003) (emphasis added) (citing *Benedi v. McNeil-PPC.*, 66 F.3d 1378, 1384 (4th Cir. 1995) ("Under the *Daubert* standard, epidemiological studies are not necessarily required to prove causation, as long as the methodology employed by the expert in reaching

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<sup>16</sup> The cases cited in 3M's opening and reply memoranda recognize as much. *See, e.g., In re Zolof Prods. Liab. Litig.*, 176 F. Supp. 3d 483, 492 (E.D. Pa. 2016) ("Epidemiological evidence is not required to establish general causation."). 3M's cases even cite the Eighth Circuit's decision in *Glastetter* for the proposition that "the absence of epidemiological evidence does not doom a plaintiff's case," yet 3M ignores that language. *Id.* at 492 n.49.

<sup>17</sup> 3M also fails to advise the Court that the section of the *Reference Manual on Scientific Evidence* that it relies on specifically pertains to the *Reference Guide on Epidemiology*.

his or her conclusion is sound.”)). Here, Drs. Jarvis and Stonnington have both applied well-accepted scientific methods in concluding that Bair Hugger can and has caused DJI.

*1. Dr. Jarvis’s opinion on general causation does not depend on the Bradford Hill criteria or the estimate of risk reported in McGovern.*

In opining that Bair Hugger can cause DJI, Dr. Jarvis applies the “gold standard” methodology he developed over 17 years at the CDC, where he was “responsible for more outbreak investigations than anyone else in the world.” Dkt. 1813-1 at 3–4 (Jarvis Rpt. at 2). Using the “exact same methodology that [he] found effective in [his] work at the CDC,” Dr. Jarvis examines the etiology of SSI versus DJI, analyzes peer-reviewed literature regarding the mechanism of infection, investigates the impact of increased particle counts on air quality in orthopedic surgeries, compares Bair Hugger to other devices with similar mechanisms of infection, and ultimately concludes based on the great weight of evidence that Bair Hugger causes or substantially contributes to DJI in orthopedic patients. *Id.* at 5–26; *see also In re Heparin Prods. Liab. Litig.*, 803 F. Supp. 2d at 726–27 (collecting cases allowing causation testimony based on methodologies other than Bradford Hill); *Milward*, 639 F.3d at 17–20 (stating that the “weight of the evidence” approach, which involves consideration of the totality of available data, is also a reliable method of causal inference).

Dr. Jarvis does not heavily rely on McGovern in so concluding. He cites the study only twice in his report and does not emphasize its estimate of risk. Dkt. 1813-1 at 11–15. The first citation states that Bair Hugger “generates convections currents that mobilized floor air into the surgical site,” but Dr. Jarvis also cites Legg 2011, Dasari 2012, Legg 2012, Belani 2013, Sessler 2013, and Dr. Elghobashi’s CFD for the same proposition. *Id.* at 11–



12. Likewise, the second citation briefly notes that McGovern reported increased DJI rates from using Bair Hugger, but Dr. Jarvis cites two other “*publications linking Bair Hugger FAWs with infections.*” *Id.* at 12–13 (emphasis added). Bernards et al. “identified the Bair Hugger FAW as one of the medical devices that were involved in the outbreaks” of a deadly pathogen, and Wood analyzed “Bair Hugger’s infection risk” and recommended using “alternative warming technologies in ultraclean orthopedic procedures” given that risk. *Id.*

While those studies are sufficient evidence of causation separate and apart from McGovern, Dr. Jarvis also analyzes other studies showing that Bair Hugger devices have “inadequate air filtration efficiency, internal bacterial contamination (including intake and exhaust hoses), exhaust microbial contaminants, interfere with OR airflow (directional or non-directional), and can introduce particles/microbial contaminants into the surgical ‘sterile’ field.” *Id.* at 9–10 (citing Avidan 1997, Albrecht 2009, Albrecht 2011, and Reed 2013); *id.* at 14 (citing Moretti 2009 as reporting “an increase in mean bacterial load values when the Bair Hugger FAW was employed”). And to rebut 3M’s unfounded argument that Bair Hugger blankets protect patients against the device’s internal contamination, Dr. Jarvis cites medical data proving that “Bair Hugger FAW blankets are *not* secondary filters of the exhausted air.” *Id.* at 13 (citing Tsai 2016); *id.* at 14 (“Bair Hugger FAWs exhaust this contaminated air into the OR/sterile surgical field through the exhaust hose and the blanket.”). He therefore opines that Bair Huggers “markedly increase the bioburden (i.e., particulates and CFUs) of the OR *directly* (via exhaust air) and *indirectly* by disruption of OR air ventilation (directional or non-directional) through the excess heat.” *Id.* at 13–14.

Dr. Jarvis then combines this mechanistic evidence of internal contamination and airflow disruption with epidemiologic evidence of the relationship between particles, bacteria, and DJI. *Id.* at 15–16, 25. Stocks “showed that particulates are a reasonably proxy for airborne bioburden,” while the Darouiche randomized controlled trial “demonstrated that particulate counts correlate with microbial counts (i.e., CFUs) and that elevated particulate counts/microbial counts at the incision site were associated with increased [DJI] risk.” *Id.* at 25. Notably, Darouiche found a statistically significant association between particles and bacteria as well as bacteria and DJI. *Id.* (“[E]very 10 CFU/m<sup>3</sup> increase in the median CFU density approximately *doubled* the probability of implant infection.”) (emphasis added); *id.* at 16–18 (citing additional published and peer-reviewed studies showing that “as few as 1-10 CFUs are required to cause” DJI). Based on the totality of evidence, Dr. Jarvis concludes that Bair Hugger increases risk of DJI for orthopedic patients because it increases particles and CFUs over the sterile surgical field. *Id.* at 25–26; *id.* at 24 (“the mechanism of infection with [Bair Hugger] is virtually identical to that documented with the [heater-cooler units],” which also increases airborne contamination).

Therefore, Dr. Jarvis’s general causation opinion does not depend on the Bradford Hill criteria or the estimate of risk reported by McGovern et al. Such epidemiologic evidence is *helpful but not necessary* here given the well-established “mechanism of causation.” *Reference Manual* at 609 n.180 (declaring that “causation can be established without epidemiologic evidence [w]hen the mechanism of causation is well understood”).

2. *Dr. Stonnington's opinion on general causation does not depend on the Bradford Hill criteria or the estimate of risk reported in McGovern.*

Dr. Stonnington also does not use the Bradford Hill criteria in opining that Bair Hugger can cause DJI. Instead, he relies on his “medical training, education, and knowledge, as well as [his] clinical experience in the field of orthopedic surgery and joint replacement.” Dkt. 1813-3 at 3. Albeit to a “lesser extent,” he further relies on the “relevant literature, the reports of other experts, and deposition testimony given in this case.” *Id.* Combining professional clinical experience with peer-reviewed literature is a well-recognized and reliable method of causal inference. *See In re Heparin Prods. Liab. Litig.*, 803 F. Supp. 2d at 727 (citing cases allowing physicians to rely on their professional clinical experience and peer-reviewed literature to opine about general causation); *see also Glaser v. Thompson Med. Co.*, 32 F.3d 969, 972 (6th Cir. 1994) (same); *Huggins v. Stryker Corp.*, 932 F. Supp. 2d 972, 991–94 (D. Minn. 2013); *Kloss*, 2013 WL 268936, at \*7–9.

Nor does Dr. Stonnington hinge his opinions on McGovern. In fact, he never even cites the 3.8 odds ratio reported therein. He simply notes that “a clinical study of patients in a United Kingdom hospital found a higher incidence of infected total joint replacements in Bair Hugger patients versus non-Bair Hugger patients.” *Id.* at 7. Rather than predicate his opinion on one study, Dr. Stonnington relies on the totality of evidence, first discussing the importance of minimizing known sources of contamination in orthopedic surgeries. *Id.* at 4. Citing the Stocks study and the Darouiche randomized controlled trial, for example, he explains that “airborne contamination is correlated with postoperative joint replacement

infections.” *Id.* He then pairs that data with evidence that Bair Hugger increases airborne contamination based on two mechanisms—internal contamination and airflow disruption.

As to the first mechanism of infection, Dr. Stonnington cites many of the same studies as Dr. Jarvis, which show that Bair Hugger “emit[s] airborne contamination into an OR environment despite the use of the filter.” *Id.* at 6. But he also cites other studies such as Baker 2002, which found “*insufficient evidence* to justify the routine use of forced-air warming units as an intraoperative measure during *ultraclean orthopedic surgery*.” Dkt. 1813-4 at 2–3. Based on those studies as well as a case report showing that the “blanket does not prevent internal soot from being transferred from the [device] and then blown through the blanket and onto the patient,” Dr. Stonnington opines that “the lack of adequate filtration in the Bair Hugger causes contamination to circulate in the OR and over the operative field, which increases the risk of patients developing [DJI].” Dkt. 1813-3 at 7–8.

As to the second mechanism of infection, Dr. Stonnington relies on the same airflow disruption studies as Dr. Jarvis. *See id.* at 7. These studies, he says, “elucidate how contaminants migrate from non-sterile regions to sterile operative wounds under a mass flow of FAW, i.e., air from a Bair Hugger device.” *Id.* He thus determines that “the Bair Hugger system causes an increased risk of patient infection because of substantial scientific evidence that the waste heat generated by the [device] disrupts operating room airflow conditions and contributes to mobilization of microbes in the area of the sterile field.” *Id.*

Combining both mechanisms of infection with his clinical experience as an orthopedic surgeon as well as epidemiological evidence regarding the relationship between particles and DJI, Dr. Stonnington ultimately concludes that “use of the Bair Hugger in

orthopedic surgeries disrupts operating room airflow and exposes patients to pathogenic contamination, thereby increasing the risk of infection in every orthopedic implant surgery case where it is used.” *Id.* at 9. Thus, Dr. Stonnington’s opinion on general causation does not depend on the Bradford Hill criteria or the estimate of risk reported by McGovern. Again, such epidemiologic evidence is *helpful but not necessary* here given the well-settled “mechanism of causation.” *Reference Manual* at 609 n.180 (“causation can be established without epidemiologic evidence [w]hen the mechanism of causation is well understood”).

3. *Dr. Jarvis’s opinions on specific causation in multiple bellwether cases do not depend on the estimate of risk reported in McGovern.*

As with his general causation opinion, Dr. Jarvis’s specific causation opinions do not depend on the Bradford Hill criteria or McGovern. In *Gareis*, *Axline*, and *Trombley*, he applied a differential diagnosis and/or etiology in concluding that Bair Hugger more likely than not caused the plaintiff’s DJI. *See, e.g., Gareis*, Dkt. 60 at 7. In all of those cases, moreover, Dr. Jarvis’s diagnosis depended on “the most likely *mechanistic source* of the bacteria that inoculated the joint,” not the estimate of risk reported in McGovern. *See id.*

In “ruling in” Bair Hugger as a potential cause of Mr. Gareis’s DJI, Dr. Jarvis emphasized that “Bair Hugger has two mechanisms for contaminating the operative field with bacteria,” each of which “causes increased squames and therefore bacteria over the sterile field.” *Id.* at 9. And when determining that Bair Hugger was the most likely cause of bacteria inoculating the joint, he opined that “the McGovern study and/or Dr. Elghobashi’s CFD model paired with the Stocks and Darouiche studies *each independently* confirm that the Bair Hugger is the most likely cause of [DJI].” *Id.* at 12 (emphasis added).

Put differently, Dr. Elghobashi's CFD combined with epidemiologic evidence regarding the relationship between particles, bacteria, and DJI is *one sufficient method* of proving specific causation, whereas "[t]he risk ratio reported by McGovern et al. *further* shows that Bair Hugger is the most likely cause of bacteria inoculating the implant." Dkt. 1792 at 13 (Jarvis *Trombley* Rpt. at 12) (emphasis added). Accordingly, Dr. Jarvis's specific causation opinions have thus far depended on the same mechanistic and epidemiologic evidence cited in his general causation report rather than the estimate of risk reported by McGovern et al.

*4. Dr. Stonnington's opinions on specific causation in multiple bellwether cases do not depend on the estimate of risk reported in McGovern.*

The same holds true with respect to Dr. Stonnington's specific causation opinions. Like Dr. Jarvis, he applied a differential diagnosis or etiology that depended on "the most likely *mechanistic source* of the bacteria that inoculated Mr. Gareis' implant." *Gareis*, Dkt. 61 at 3. Because his differential diagnosis was based upon the most likely mechanistic source of inoculation rather than the estimate of risk reported in McGovern, Dr. Stonnington never ever cited McGovern. *Id.* at 2–5. In short, Dr. Stonnington relied on the same mechanistic evidence that he cited in his general causation report in concluding that Bair Hugger rather than any other potential factor was the most likely cause of inoculation.

## CONCLUSION

For these reasons, as well as the reasons stated in Plaintiffs' memorandum in opposition to 3M's motion for reconsideration, the Court should deny 3M's motion in full.

Respectfully submitted,

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